UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,472	03/26/2001	Wilson Smart	Kuml1Si1.Prb	6422

7590 07/25/2003

PENNIE & EDMOND, LLP
1155 AVENUE of the AMERICAS
NEW YORK,, NY 10036-2711

EXAMINER
NASSER, ROBERT L

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,472	SMART ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-31,34 and 36-56* is/are pending in the application.

4a) Of the above claim(s) *28-30 and 38-47* is/are withdrawn from consideration.

5)☐ Claim(s) *48 and 49* is/are allowed.

6)☐ Claim(s) *1-10,12-27,31,34,36,37 and 50-56* is/are rejected.

7)☐ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11, 14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 28-30 and 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 54 recites that the substrate has curved sides in the z direction. The examiner sees no support for this limitation in the disclosure. Hence it constitutes new matter.

Claims 2 and 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 51 is a substantial duplicate of claim 2.

Before applying art, the examiner notes that the term "silicon substrate" is being interpreted to mean that the substrate is made only of silicon, as opposed to the silicon dioxide substrate taught by Say et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 12, 27, 31, 37, 51-53, 55, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al 5,591,139. Lin et al shows a device including a silicon substrate 10 having a x (length) y (width) and z dimension, where the top and bottom surfaces extend in the x and y dimension, where the substrate has a body portion 12 at a body end and a penetration end 18, and a biosensor 104 integrated into the substrate (see figure 6). With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the Y direction. With respect to claims 5-8, the substrate has a length in the x directions of 2.5-7.5 mm (see figure 2A and the accompanying discussion), where the penetration depth is 1-6 mm. In addition, the y dimension depth at the penetration depth is 80 micrometers, which is "about" 30 and the Y dimension width at the body end is 140 micrometers, which is "about" 200 micrometers. Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure in figure 6

for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. Claim 27 is rejected in that the sensor is "near" the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claim 37 is rejected in that the substrate is single crystal silicon. Claims 51-53, 55, and 56 are rejected for the reasons given above.

Claims 1-8, 10, 12, 25-27, 31, 32, 34, 36-37, 50-53, 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Frazier et al WO 01/93930. Frazier et al has a silicon substrate has a body portion 18 and a penetration portion 11, with a biosensor 17 mounted on the penetration portion.). With respect to claims 2-4, the penetration portion end tapers from the body to a tip at the penetration end, where the taper is uniform in the Y direction. With respect to claims 5-8, the substrate has the recited dimensions (see columns 9 and 10). Claim 10 is rejected in that the point is a symmetrically shaped point. Claim 12 is rejected in that there is structure discussed in column 7, lines 21-26 for interfacing with an analyte meter and there is a signal carrier between the sensor and the interface. Claim 5 is rejected in that the sensor is optical. Claim 26 is rejected in that the sensor is spaced enough from the body portion to penetrate into the body. Claim 27 is rejected in that the sensor is near the penetration end. Claim 31 is rejected in that the biosensor is on a planar surface of the substrate. Claims 34 and 36 are rejected in that there are multiple biosensors and different x dimension depths. Claim 37 is rejected in that the substrate is single crystal silicon. Claim 50 is rejected in the, in addition to the reasons given above, there are multiple

biosensors sensing multiple parameters. Claims 51-53, 55, and 56 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 13-15, 18, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Lin et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. With respect to claim 13, Lin et al does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify Lin et al to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. With respect to claims 14 and 15, Lin et al teaches an ion chip analyzer, 104, but does not state what kind of analyzer it is. Say et al uses a electrochemical analyzer. Hence, it would have been obvious to modify Line t al to use an electrochemical analyzer, as it is merely the substitution of one known equivalent analyzer for another. Claim 18 is rejected in that here is an electrically insulation silicon dioxide layer 54 on the substrate. Claim 20 is rejected in that all the electronic components are deposited on the Sio2 layer (see column 8, lines 1-14). Therefore, it

would seem clear that the biosensor 104 would also be on the Sio2 layer. Claims 21-24 are rejected in that the examiner takes official notice that the techniques recited are well known techniques used to deposit contacts on a substrate and therefore it would have been obvious to modify the above combination et al to use the recited techniques.

Claims 9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Say et al. With respect to claim 9, Say et al shows a chisel shaped microneedle. Therefore, it would have been obvious to modify Frazier et al to use the needle shape taught by Say et al, as it is merely the substitution of one known equivalent needle shape for another. With respect to claim 13, Frazier does not teach how the device is attached to the external device. Say et al shows a similar analyte monitoring device where the microneedle device is attached to the external device with contact pads 49. Hence, it would have been obvious to modify Lin et al to use such an attachment technique, as it is merely the selection of a well known attachment technique in the art. With respect to claims 14 and 15, Frazier uses an electrochemical sensor to measure analyte levels.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al, as applied to claims 9, 13-15, 18, and 20-24, further in view of in view of Meade et al. Meade teaches that electrogravometric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravometric sensor, as it is merely the substitution of one known equivalent for another.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al in view of Say et al, as applied to claims 9 and 13-15, further in view of in view of Meade et al. Meade teaches that electrogravometric sensors and electrochemical sensors are equivalent for analyte monitoring. Hence, it would have been obvious to modify the above combination to use an electrogravometric sensor, as it is merely the substitution of one known equivalent for another.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Say et al, as applied to claims 9, 13-15, 18, and 20-24, further in view of in view of Kim et al. Kim et al shows a silicon oxide insulative layer on the substrate. It would have been obvious to modify the above combination to use the silicon oxide layer in place of the silicon dioxide layer, as it is merely the substitution of one well known insulative layer for another.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Smart 5,801,057. Smart teaches the use of an optical sensor to measure analyte levels. Hence, it would have been obvious to modify the above combination to use an optical sensor, as it is merely the substitution of one known equivalent for another.

Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al in view of Kim et al. With respect to claims 34 and 36, Lin et al only has a single analyte sensor. Kim et al shows multiple sensors for measuring glucose to increase accuracy of measurement. Hence, it would have been obvious to modify Lin et al to include multiple sensor, to increase the accuracy.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. The shape of the z dimension thickness appears to be for no purpose and solves no stated problem. Therefore, it is the examiner's position that the exact shape is a mere matter of design choice for one skilled in the art.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. The shape of the z dimension thickness appears to be for no purpose and solves no stated problem. Therefore, it is the examiner's position that the exact shape is a mere matter of design choice for one skilled in the art.

Claims 48 and 49 are allowable.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 11 defines over the art in that none of the art teaches the microfillet portion. In view of the discussion on page 12 of the specification, it is clear that the inclusion of such a portion is more than merely a change in shape and therefore defines over the art of record.

Applicant's arguments filed 5/12/2003 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser
Primary Examiner
Art Unit 3736

RIn
July 24, 2003

ROBERT L. NASSER
PRIMARY EXAMINER